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10/780,152	02/17/2004	Andreas Hefel	RBL0109	1277

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BAKER & DANIELS LLP
111 E. WAYNE STREET
SUITE 800
FORT WAYNE, IN 46802

EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,152	HEFEL, ANDREAS	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/18/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's Arguments/Remarks, amended claims, IDS and RCE filed on 02/18/08 is acknowledged.

Claims 1-20 remain cancelled in this Application, new claims 30-33 have been added.

Accordingly, claims 21-33 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 21-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The following claims are very broad:

Claim 21 (Currently amended): A process for providing a human or animal with at least two active substances, comprising: providing a polysaccharide in the form of a plurality of granular particles ,including a first active substance incorporated into a first granular particle and a second active substance incorporated into a second granular particle, wherein the first and second granular particles are functionally separated from one another and the active substances thereof do not mix or interact with one another; an d introducing the polysaccharide into a metabolism of a human or animal, in which the active substances are released in a delayed release fashion into blood of the human or animal and the polysaccharide and active ingredients embedded therein are adapted to one or more specific needs of the human or animal.

Claim 22 (Previously presented): The process of Claim 21, wherein the polysaccharide comprises at least one polysaccharide selected from the group consisting of galactomannans and glucomannans.

Vas-Cath Inc. V. Mahurkar, *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111, (Fed. Cir. 1991), states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (p. 1117). A review of the language of the claims 24 and 25 indicate that these claims are drawn to a genus, i.e., a "polysaccharide and galactomannan and glucomannons.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide

an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states, "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Limitations from the specification cannot be read into the claims and the claims must be given their broadest reasonable interpretation (see MPEP 2111). During examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004). In light of the foregoing, the term "polysaccharide ,galctomannan and glucomannon reads on any species that falls under the genus.

(Prior art WO 99/06023 discloses that the term "galactomannan" refers to polysaccharides derived the natural gums or similar natural or synthetic gums containing mannose or galactose moieties, or both groups, as the main structural components. Preferred galactomannans of the present invention are made up of linear chains of (1-4)-.beta.-D-mannopyranosyl units with .alpha.-D-galactopyranosyl units attached by (1-6) linkages. With the preferred galactomannans, the ratio of D-galactose to D-mannose varies, but generally will be from about 1:2 to 1:4. Galactomannans having a D-galactose:D-mannose ratio of about 1:2 are most preferred. Additionally, other chemically modified variations of the polysaccharides are also included in the "galactomannan" definition. For example, hydroxyethyl, hydroxypropyl and carboxymethylhydroxypropyl substitutions may be made to the galactomannans of the present invention. Non-ionic variations to the galactomannans, such as those containing alkoxy and alkyl (C1-C6) groups are particularly preferred when a soft gel is desired (e.g., hydroxylpropyl substitutions). Substitutions in the non-cis hydroxyl positions are most preferred. An example of non-ionic substitution of a galactomannan of the present invention is hydroxypropyl guar, with a molar substitution of about 0.4. Anionic substitutions may also be made to the galactomannans. Anionic substitution is particularly preferred when strongly responsive gels are desired).

Based on the above, it is the position of the examiner that the genus polysaccharide/galactomannan and glucomannan reads on even substituted galactomannans as disclosed in prior art for which applicants have not shown

possession. In the absence of specific polysaccharide/galactomannan and glucomannan, the claim as recited lacks written description requirements. The disclosure specifies only single polysaccharide which is guar, however no other representative examples have been set forth in the disclosure.

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claims encompass numerous species that are not further described. While "examples explicitly covering the full scope of the claim language" typically will not be required, a sufficient number of representative species must be included to "demonstrate that the patentee possessed the full scope of the [claimed] invention." Lizardtech v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005).

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is a polysaccharide or galactomannan or glucomannan due to which the release rate will be delayed. The delayed release profile claimed is due to polysaccharide, however it is a well known fact that all polysaccharides have their own structural characteristics which is associated with their functional characteristics. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (see, Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord Ex Parte Kubin, 2007-0819, BPAI 31 May 2007, opinion at p. 16, paragraph 1). The specification does not clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 23-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites the limitation "desired particle size". The term is indefinite and unclear. It is unclear as to what applicant means by "desired particle size".

The rejection is maintained.

The term "desired particle size in claim 24 is a relative term which renders the claim indefinite. The term "desired particle size" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Although applicant has added claim particle size in claim 33, however, claim 24 is still indefinite for not reciting the desired particle size. Applicant's argument that the desired particle size has been disclosed in specification is noted by the examiner. However, the claims are given broadest reasonable interpretation during prosecution and also in light of MPEP:

(USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d

1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily). In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Examiner suggests reciting specific particle size in claim 24 in order to distinctly claim the subject matter as the applicant regards as invention.

Claim 27 recites the limitation "gradual". Gradual is a relative term which renders the claim indefinite. Examiner suggests reciting specific release rate. Claim 30 recites the limitation "do not does exceed physiological levels" which makes the claim indefinite. It is not clear which physiological needs is the applicant referring to. The limitation "sustained supply is a relative term which makes the claim indefinite in claim 31. Examiner suggests reciting specific release rate.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 21-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2257358 A.

GB 2257358 A discloses a composition comprising vitamins, enzymes, coenzymes, minerals, trace elements and/or microorganisms that are embedded, separately with regard to function, in carrier substances with formation of protective films against harmful effects so that, with sufficient moisture absorption, in vivo and in vitro biocatalytic processes can be initiated and controlled. Suitable protective substances are preferably sodium salts and potassium salts of silicic acid and nonionic polysaccharides, in particular from the family consisting of the galactomannans (page 2, paragraph 2 and **claim 5**). The process of mixing and drying is depicted on page 4, paragraph 4, page 7, paragraph, 1 and in example 2). It is further disclosed that the **granulation** can be influenced by the spraying rate and the enzyme powders are obtained in relatively narrow particle size ranges after drying (page 8, paragraph 1). It is to be noted that claims 25-28 provide the functional limitations once the active substance is introduced into human or animal, since the claimed compound is similar to the compound disclosed in the prior art, the functional limitations are considered associated to the process. Based on the teachings of the prior art, it would have been obvious to one of ordinary skilled in the art at the time of the instant invention to formulate a process of providing a human or animal a composition comprising two active ingredients with no antagonistic interactions between the two. A skilled artisan would thus have arrived to claimed invention of providing a human or animal with at least two active substances comprising polysaccharide in the form of granules with a

reasonable expectation of success.

Response to Arguments

8. Applicant's arguments filed 09/19/2007 have been fully considered but they are not persuasive. Applicant argues "that the prior art does not disclose the added new limitation of a step of adapting a polysaccharide to the specific needs of a human or people."

These arguments are not persuasive because the essential elements of the claim which is active ingredient and polysaccharide are disclosed in the prior art, therefore it is obvious that the release profile associated with the disclosed components will cater to the specific needs of a human or animal.

In response to this argument that the prior art does not teach the claimed new limitation that the active substances do not antagonize each other and the drug is released in a delayed fashion into blood of human or animal , the examiner points to the paragraph 2 and claim 5 which states that vitamins, enzymes, coenzymes, minerals, trace elements and/or microorganisms that are embedded, separately with regard to function, in carrier substances with formation of protective films against harmful effects so that, with sufficient moisture absorption, in vivo and in vitro biocatalytic processes can be initiated and controlled. Galactomannans are used in the process (see page 2, paragraph 2). In terms of the coenzymes which can be embedded in the carrier material, it is stated in the prior art that the sensitivity of the highly complicated polypeptide complexes makes it appear appropriate to have available, quantitatively separate and qualitatively protected enzymes for biocatalytic processes. Thus the importance of introducing the

active substances separately in order to maintain the qualitative and quantitative parameters of the substance is depicted in the prior art. Further emphasis on this limitation is evident from page 4, paragraph 2. Furthermore the newly added limitation of the active ingredient being released in the delayed fashion is due to the structural characteristics of the polysaccharide/glucomannan/galactomannan which has not been disclosed in claim 1. Claim 1 generically recites polysaccharide. Polysaccharides are known in the art to cause delay in the release of active drug. Specifically in the absence of representative no. of polysaccharides, any specific release rate, specific amount of the active ingredient and specific particle size , it is the position of the examiner that the prior art renders the claimed invention obvious as claimed.

It should be noted that Applicant has not defined specific particle size, in the absence of such; the generic recitation of particle will read on any particle size. Furthermore, the preamble of the claim is directed to a "process for providing a human or animal with atleast two active substances", the prior art cited teaches the same as discussed above in the rejection.

The rejection is therefore maintained.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/
Examiner, Art Unit 1612
/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612